## SMDA 510(k) Summary of Safety and Effectiveness

(1) Submitter's name / Contact person:

Aerogen Inc.
1310 Orleans Drive
Sunnyvale, CA 94089

**Contact person:** Traci V. A. Edwards
Senior Director, Quality Assurance & Regulatory Affairs
Tel.: (408) 543-2414
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**Date prepared:** March 2002

(2) Name of device:

**Trade name:** Aeroneb® Professional Nebulizer System (Aeroneb Pro)
**Common name:** Nebulizer
**Classification name:** Nebulizer, 21 CFR §868.5630

(3) Identification of predicate device:

| Manufacturer | Device | 510(k) Number |
|---|---|---|
| Aerogen Inc. | Aeroneb® Portable Nebulizer System | K970010/ K003022 |
| Siemens-Elena AB | Siemens Servo Ultra Nebulizer (SUN), Models 354 and 145 | K960854 |

(4) Description of the device:

The Aeroneb® Professional Nebulizer System is a multiple patient reusable pulmonary drug delivery system that incorporates Aerogen's proprietary aerosol generator technology for continuous nebulization of drugs to patients. The Aeroneb Pro is designed to be used with mechanical ventilators and pressurized breathing systems as well as by spontaneously breathing patients. It is intended for multiple patient use and is autoclavable. The nebulizer can be placed in the inspiratory limb of a ventilator circuit or used with a mask or mouthpiece. The Aeroneb Pro operates without changing patient ventilatory parameters, can be refilled without interrupting ventilation, and can be powered by AC/DC adapter or internal rechargeable battery. Because the Aeroneb Pro operates without compressed gas and can be battery-powered, it is also suitable for use during patient transport.

(5) A statement of the intended use of the device:

The Aeroneb® Professional Nebulizer System is a portable medical device for multiple patient use that is intended to aerosolize physician-prescribed solutions for inhalation to patients on and off ventilation and other positive pressure

breathing assistance. The Aeroneb Pro is suitable for use in adult and pediatric patients as described in the Instruction Manual.

(6) Predicate device comparison:

The Aeroneb Pro is substantially equivalent to similar features in the predicate devices and has the same intended use and technological characteristics as the predicate devices.

Non-clinical performance tests were conducted comparing Aeroneb Pro to the Aeroneb Portable Nebulizer System and SUN 145.

(7) Performance evaluations

Evaluation of performance included nebulizer delivery characterization, electrical, mechanical, and EMC safety, were based on those suggested in the FDA CDRH - REVIEWER GUIDANCE FOR NEBULIZERS, METERED DOSE INHALERS, SPACERS AND ACTUATORS issued on: October 1, 1993.

The successful tests demonstrated the device consistently performed within its design parameters, is as safe and effective, and performs as well as, or better than, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 5 2002

Aerogen, Inc.
c/o Mr. Mark Job
TUV America, Inc.
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K021175
Aeroneb® Professional Nebulizer System
Regulation Number: 868.5630
Regulation Name: Nebulizer (Direct Patient Interface)
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: April 29, 2002
Received: April 30, 2002

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):** K021175

**Device Name:** Aeroneb® Professional Nebulizer System

**Indications for Use:**

The Aeroneb® Professional Nebulizer System is a portable medical device for multiple patient use that is intended to aerosolize physician-prescribed solutions for inhalation to patients on and off ventilation or other positive pressure breathing assistance. The Aeroneb® Professional Nebulizer System is suitable for use in adult and pediatric patients as described in the Instruction Manual.



(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANTOHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021175

Prescription Use_____ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Optional Format 1-2-96)

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